AWARD NUMBER: W81XWH-15-2-0062

TITLE: Prostate Cancer Biospecimen Cohort Study

PRINCIPAL INVESTIGATOR: Bettina F. Drake, MPH, PhD

CONTRACTING ORGANIZATION: Washington University
Saint Louis, MO 63130

REPORT DATE: October 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
October 2017	Annual	30 Sep 2016 - 29 Sep 2017

4. TITLE AND SUBTITLE
Prostate Cancer Biospecimen Cohort Study

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-2-0062

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Bettina F. Drake, PhD, MPH
Associate Professor

E-Mail: drakeb@wustl.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
WASHINGTON UNIVERSITY
ONE BROOKINGS DR
SAINT LOUIS MO 63130-4862

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The goal of the study is development of a Prostate Cancer Biorepository Network (PCBN) resource site with high quality and well-annotated urine, blood, and tissue specimens as part of a multi-institutional Department of Defense collaboration. De-identified data, tissue and other biospecimens will then be available through the sites to all prostate cancer investigators to conduct further research. This is a collaborative effort among the sites with no coordinating center and each site will be responsible for maintaining/storing their own data/samples.

15. SUBJECT TERMS
Prostate cancer, disparities, biorepository, active surveillance, high risk

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
					USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**	Unclassified	9	**19b. TELEPHONE NUMBER** *(include area code)*
Unclassified	Unclassified	Unclassified			

Standard Form 298 (Rev. 8-98)

Table of Contents

Page

1. INTRODUCTION:

The goal of the study is development of a Prostate Cancer Biorepository Network (PCBN) resource site with high quality and well-annotated urine, blood, and tissue specimens as part of a multi-institutional Department of Defense collaboration. De-identified data, tissue and other biospecimens will then be available through the sites to all prostate cancer investigators to conduct further research. This is a collaborative effort among the sites with no coordinating center and each site will be responsible for maintaining/storing their own data/samples.

2. KEYWORDS:

Prostate cancer, biorepository, disparities, active surveillance, high risk

3. ACCOMPLISHMENTS:

What were the major goals of the project?

1. Team Meeting
    a. Review grant and progress of recruitment in parent study – Year 1, Month 1 – 100% complete
    b. Team Meetings will occur monthly throughout the award – Year 1-2, Monthly – 100% complete
    c. Meetings with Tissue Procurement Core – Year 1-2, Monthly – 100% complete
2. Protocol Development
    a. Meet with Tissue Procurement Core and the Resource Site Coordinator to finalize protocol – Year 1, Month 3 – 100% complete
    b. Train Recruiter and Data Manager on protocol to use for recruitment and data entry – Year 1, Month 3-4 – 100% complete
3. Regulatory review and Institutional Review Board (IRB)
    a. Complete and submit forms for regulatory review – Year 1, Month 3-4 – 100% complete
    b. Complete and submit IRB forms for review – Year 1, Month 3-4 – 100% complete
    c. Obtain approval for regulatory and IRB forms – Year 1, Month 4 – 100% complete
4. Recruitment – Ongoing in No Cost Extension
    a. Active surveillance patients – Year 1, Month 5-12
    b. High risk patients – Year 1, Month 5-12
    c. African American patients – Year 1, Month 5-12
    d. Recontact high risk patients from Prostate Cancer Prospective Cohort– Year 1, Month 6-12
5. PCBN-related travel
    a. PCBN EAB meetings – Year 1, – 100% complete
    b. 1-day meeting to present on progress at Integration Panel – Year 1, – 100% complete
6. Pathological review
    a. Site visits by Dr. Humphrey (urological pathologist) – Year 1, Month 6 – 100% complete
    b. Regular review by Dr. Sehn – Year 1, Month 6 – 100% complete

What was accomplished under these goals?

1. Grant reviewed and parent study accessed for high-risk patients to recontact. Team meetings and meetings with TPC for study development.
2. Protocol developed and finalized for regulatory submission. Recruiter hired and trained along with data manager.
3. Protocol and application submitted to IRB, and approval letters obtained.
4. Recruitment

	Prostate Cancer Prospective Cohort Banked Biospecimens	Biospecimen Acquisition March 2016 – October 2017	Total Banked Specimens
Plasma/Serum/Cell Pellet* **			
Total High-risk	320	30	350
African American	38	4	42
Total Active Surveillance	N/A	20	20
African American	N/A	4	4
Intermediate Risk	N/A	11	11
Low risk African Americans (not on Active Surveillance)	N/A	4	4
Total Plasma/Serum/Cell	**320**	**65**	**385**
Urine			
Total High-risk	N/A	30	30
African American	N/A	4	4
Total Active Surveillance	N/A	20	20
African-American	N/A	4	4
Intermediate Risk	N/A	11	11
Low Risk African Americans (not on Active Surveillance)	N/A	4	4
Total Urine	**N/A**	**65**	**65**
Tissue			
Total High-risk	243	11	254
African American	26	2	28
Total Active Surveillance	N/A	0	0
African-American	N/A	0	0
Intermediate Risk	N/A	6	6
Low Risk African Americans (not on Active Surveillance)	N/A	2	2
Total Tissue	**243**	**19**	**262**
TOTAL SPECIMENS	**563**	**149**	**712**
***Only serum and cell pellet available on Prostate Cancer Prospective Cohort			

a. Recruitment started in March of 2016 and there are currently 82 newly diagnosed patients consented.

i. Active surveillance patients: 22
Active Surveillance African American patients: 5

ii. High risk patients: 34
High risk African American patients: 5

b. An amendment to the IRB in recruitment has been submitted to cover patients considered to be "intermediate risk" (Gleason 3+4). This was changed because 65% of patients were being missed, that were considered "low risk" previously in our study, which went on to have treatment.

i. Intermediate Risk: 9
ii. Intermediate Risk African American patients: 3

c. Recontacting patients from the Prostate Cancer Prospective Cohort study is in progress.

5. PCBN related travel
   a. PCBN EAB meeting on October 27, 2016
6. Pathological review
   b. Dr. Jennifer Sehn is the pathologist on the study and reviews all slides.
7. Sample Request: PI Wake Forest Baptist Medical Center
   a. 105 matched FFPE tissue slides (x4 slides each) and serum, along with clinical and socio-demographic variables.

What opportunities for training and professional development has the project provided?
Nothing to Report

How were the results disseminated to communities of interest?
Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?
Continue recruitment for active surveillance patients, high-risk, and African American patients. Recontact patients from the Prostate Cancer Prospective Cohort including recruitment for "intermediate risk" patients. We recently received approval for a 1-year no cost extension, therefore recruitment of participants and collection of specimens will continue. In addition, the protocol is being amended to include recruitment of all prostate cancer patients seen in clinic without prior treatment.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?
Nothing to Report

What was the impact on other disciplines?
Nothing to Report

What was the impact on technology transfer?
Nothing to Report

What was the impact on society beyond science and technology?
Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change
We were missing a significant number of patients by selecting only high-risk and active surveillance prostate cancer patients. We expanding our recruitment to include intermediate risk patients and low-risk patients who do not choose active surveillance. However, priority remains on participants with high-risk disease or who choose active surveillance.

Actual or anticipated problems or delays and actions or plans to resolve them
Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Nothing to Report

Significant changes in use or care of human subjects
Nothing to Report

Significant changes in use or care of vertebrate animals.
Nothing to Report

Significant changes in use of biohazards and/or select agents
Nothing to Report

6. PRODUCTS:

- **Publications, conference papers, and presentations**
  Journal publications.
  Nothing to Report

  Books or other non-periodical, one-time publications.
  Nothing to Report

  Other publications, conference papers, and presentations.
  Nothing to Report

- **Website(s) or other Internet site(s)**
  Nothing to Report

- **Technologies or techniques**
  Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Nothing to Report

- **Other Products**

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

1. Name: Bettina F. Drake, PhD, MPH
   Project Role: Principal Investigator
   Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 3.6
Contribution to Project: Dr. Drake is the lead investigator on this study.
Funding Support: DoD Grant

2. Name: Shivani Thakkar, BS, MPH, CPH
Project Role: Recruiter
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 12
Contribution to Project: Ms. Thakkar is the recruiter on this study.
Funding Support: DoD Grant

3. Name: Danielle Rancilio, MS, MPH
Project Role: Data Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Ms. Rancilio has worked on goals related to this study including data and study management.
Funding Support: DoD Grant

4. Name: Alex Klim, RN, MHS, CCRC
Project Role: Site Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.2
Contribution to Project: Mrs. Klim has worked on goals related to study and regulatory management.
Funding Support: DoD Grant

5. Name: Jennifer Sehn, MD
Project Role: Pathologist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.6
Contribution to Project: Dr. Sehn serves as will serve as the study pathologist and leads the processing, annotation and storage of prostate biospecimens. In addition, Dr. Sehn works with consultant, Peter Humphrey, when a second opinion would be beneficial in reviewing the pathology.
Funding Support: DoD Grant

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Nothing to Report

What other organizations were involved as partners?
Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

N/A

QUAD CHARTS:

N/A

9. APPENDICES:

None